The following corrections or additions to the January 2001 list were published in the Federal Register in March 2001.

New Approvals

NADA Number: 141-140

Trade Name:	Monensin (Coban®) plus Bacitracin Methylene Disalicylate (BMD®)
Ingredients:	Monensin, bacitracin methylene disalicylate
Sponsor:	Alpharma, Inc.
Approval Date:	January 2, 2001
Status:	Over-the-counter
Route:	Oral (via feed)
Species:	Chickens
Drug Form:	Type A Medicated Articles to make two-way combination Type C medicated feeds.
Concentration:	Monensin: 45 or 60 grams of monensin activity per pound of Type A Medicated Article Bacitracin methylene disalicylate: 10, 25, 30, 40, 50, 60, or 75 grams of bacitracin methylene disalicylate activity per pound of Type A Medicated Article
Indications:	**Replacement chickens intended as cage layers**: As an aid in the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima*; for increased rate of weight gain and improved feed efficiency **Broiler chickens and replacement chickens intended as cage layers**: As an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.
Tolerance:	21CFR 556.70 Bacitracin: The acceptable daily intake for total residues of bacitracin is 0.05 milligram per kilogram of body weight per day. The tolerances for residues of bacitracin are established at 0.5 part per million, negligible residue, in uncooked edible tissues of chickens. 21CFR 556.420 Monensin: The acceptable daily intake for total residues of monensin is 12.5 micrograms per kilogram of body weight per day. A tolerance for residues of monensin in chickens is not needed.
Withdrawal:	Zero days

21CFR 558.355

ANADA Number: 200-228

Pioneer Product:	128-409
Trade Name:	Phoenectin™ Injection for Cattle and Swine
Ingredients:	Ivermectin
Sponsor:	Phoenix Scientific, Inc.
Approval Date:	December 27, 2000
Status:	Over-the-counter
Route:	Injection (subcutaneous)
Species:	Cattle, swine, reindeer, American bison
Drug Form:	Liquid (solution)
Concentration:	1% ivermectin solution
Indications:	**Cattle**: For the treatment and control of various species of gastrointestinal roundworms, lungworms, grubs, biting and sucking lice, and mange mites in beef cattle and dairy cattle not of breeding age. Gastrointestinal roundworms (adults and 4th stage larvae): *Ostertagia ostertagi* (including inhibited larvae *), O. lyrata, Haemonchus placei, Trichostrongylus axei, T. colubriformis, Cooperia oncophora, C. punctata, C. pectinata, Oesophagostomum radiatum, Bunostomum phlebotomum, Nematodirus helvetianus* (adults only), *N. spathiger* (adults only) Lungworms (adults and 4th stage larvae): *Dictyocaulus viviparus* Grubs (parasitic stages): *Hypoderma bovis, H. lineatum* Sucking Lice : *Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus* Mites (Scabies): *Psoroptes ovis* (synonym. *P. communis* var. bovis *), Sarcoptes scabiei* var. bovis

Swine: For the treatment and control of the following species of gastrointestinal roundworms, lungworms, lice, and mange mites.
Gastrointestinal roundworms : Large roundworms, *Ascaris suum* (adults and 4th stage larvae); red stomach worm, *Hyostrongylus rubidus* (adults and 4th stage larvae); nodular worm, *Oesophagostomum* spp. (adults and 4th stage larvae); threadworm, *Strongyloides ransomi* (adults only)
Somatic Roundworm Larvae : Threadworm, *Strongyloides ransomi* (somatic larvae)
Lungworms: *Metastrongylus* spp. (adults only)
Lice: *Haematopinus suis*
Mites: *Sarcoptes scabiei* var . *suis*
Reindeer: For the treatment and control of warbles (*Oedemagena tarandi.*
American Bison: For the treatment and control of grubs (*Hypoderma bovis)*

Tolerance: 21CFR 556.344: The acceptable daily intake for total residues of ivermectin is 1 microgram per kilogram of body weight per day.
A tolerance is established for 22,23-dihydroavermectin B_1a (marker residue) in liver (target tissue) as follows: cattle 100 parts per billion, swine 20 parts per billion, reindeer 15 parts per billion, American bison 15 parts per billion.
Muscle residues are not indicative of the safety of other edible tissues. A tolerance is established for 22,23-dihydroavermectin B_1a (marker residue) in muscle as follows: swine 20 parts per billion; cattle 10 parts per billion.

Withdrawal: Cattle - 35 days; Swine - 18 days; Reindeer and American Bison - 56 days;

21CFR 522.1192

ANADA Number: 200-299

Pioneer Product: 140-841
Trade Name: Iver-On™
Ingredients: Ivermectin
Sponsor: Med-Pharmex, Inc.
Approval Date: December 28, 2000
Status: Over-the-counter
Route: Topical
Species: Cattle
Drug Form: Liquid (solution)
Concentration: 5 milligrams per milliliter
Indications: For the treatment and control of the following parasites in beef cattle and dairy cattle not of breeding age:
Gastrointestinal roundworms: *Ostertagia ostertagi,* adult and fourth stage larvae including inhibited stage; *Haemonchus placei*, adults and fourth stage larvae; *Trichostrongylus axei*, adults and fourth stage larvae; *T. colubriformis*, adults and fourth stage larvae; *Cooperia spp.*, adults and fourth stage larvae; *Strongyloides papillosus*, adults; *Oesophagostomum radiatum*, adults and fourth stage larvae; *O. venulosum*, adults only; *Trichuris spp.*, adults
Lungworms: *Dictyocaulus viviparus*, adults and fourth stage larvae
Cattle grubs: *Hypoderma bovis, H. lineatum*, parasitic stages
Mites : *Sarcoptes scabiei var. bovis, Chorioptes bovis*
Lice: *Linognathus vituli, Haematopinus eurysternus, Damalinia bovis, Solenopotes capillatus*
Horn flies: *Haematobia irritans*

Tolerance: 21CFR 556.344. The acceptable daily intake for total residues of ivermectin is 1 microgram per kilogram of body weight per day.
A tolerance is established for 22,23-dihydro-avermectin B_1a in liver as 100 parts per billion. Muscle residues are not indicative of the safety of other edible tissues. A tolerance is established for 22,23-dihydroavermectin B_1a (marker residue) in muscle as 10 parts per billion.

Withdrawal: 48 days

21CFR 524.1193

Supplemental Approvals

NADA Number: 012-491

This supplemental application provides for using tylosin Type A Medicated Article to make liquid Type B medicated feed which in turn is used to make dry Type C medicated feeds.

Trade Name:	Tylan®
Ingredients:	Tylosin phosphate
Sponsor:	Elanco Animal Health
Approval Date:	February 2, 2001
Status:	Over-the-counter
Route:	Oral
Species:	Beef cattle
Drug Form:	Type A Medicated Article to make Type B and C medicated feeds.
Concentration:	40 or 100 grams of tylosin activity per pound of Type A Medicated Article
Indications:	For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces (Corynebacterium) pyogenes.*
Tolerance:	21CFR 556.740 Tylosin: A tolerance for residues of tylosin in edible products in cattle is 0.2 part per million (negligible residue) in uncooked fat, muscle, liver, and kidney.
Withdrawal:	Zero days

21CFR 558.625

NADA Number: 094-170

This supplemental application provides for the addition of a 200-milligram strength tablet.

Trade Name:	Phenylbutazone Tablets, USP 200 mg
Ingredients:	Phenylbutazone
Sponsor:	Phoenix Scientific, Inc.
Approval Date:	January 12, 2001
Status:	Prescription only
Route:	Oral
Species:	Dogs
Drug Form:	Tablet
Concentration:	200 milligrams per tablet
Indications:	For relief of inflammatory conditions associated with the musculoskeletal system in dogs.
Exclusivity:	3 years

21CFR 520.1720

NADA Number: 104-646

This supplemental application provides for use of monensin and tylosin single-ingredient Type A Medicated Articles to make combination Type C medicated feeds.

Trade Name:	Rumensin®, Tylan®
Ingredients:	Monensin sodium, tylosin phosphate
Sponsor:	Elanco Animal Health
Approval Date:	February 2, 2001
Status:	Over-the-counter
Route:	Oral
Species:	Cattle (fed in confinement for slaughter)
Drug Form:	Type A Medicated Articles to make Type C medicated feeds
Concentration:	Monensin: 20, 30, 45, 60, 80, or 90.7 grams of monensin activity per pound of Type A Medicated Article Tylosin: 10, 40, or 100 grams of tylosin activity per pound of Type A Medicated Article
Indications:	For improved feed efficiency; prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*; and for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces (Corynebacterium) pyogenes*.
Tolerance:	21CFR 556.420 Monensin: The acceptable daily intake for total residues of monensin is 12.5 micrograms per kilogram of body weight per day. A tolerance of 0.05 ppm is established for negligible residues of in the edible tissues of cattle. 21CFR 556.740 Tylosin: A tolerance of 0.2 ppm for negligible residues of tylosin in uncooked fat, muscle, liver, and kidney.
Withdrawal:	Zero days

21CFR 558.355

NADA Number: 104-646

This supplemental application provides for using monensin and tylosin Type A Medicated Articles to make liquid Type B medicated feeds used in turn to make dry Type C medicated feeds.

Trade Name:	Rumensin®, Tylan®
Ingredients:	Monensin sodium, tylosin phosphate
Sponsor:	Elanco Animal Health
Approval Date:	February 2, 2001
Status:	Over-the-counter
Route:	Oral
Species:	Cattle fed in confinement for slaughter
Drug Form:	Type A Medicated Articles to make Type B and C medicated feeds.
Concentration:	Monensin: 20, 30, 45, 60, 80, or 90.7 grams of monensin activity per pound of Type A Medicated Article Tylosin: 40 or 100 grams of tylosin activity per pound of Type A Medicated Article
Indications:	For improved feed efficiency and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces (Corynebacterium) pyogenes.*
Tolerance:	21CFR 556.420 Monensin: The acceptable daily intake for total residues of monensin is 12.5 micrograms per kilogram of body weight per day. A tolerance of 0.05 part per million is established for negligible residues of monensin in edible tissues of cattle. 21CFR 556.740 Tylosin: A tolerance for residues of tylosin in edible products in cattle is 0.2 part per million (negligible residue) in uncooked fat, muscle, liver, and kidney.
Withdrawal:	Zero days

21CFR 558.355 and *558.625*

NADA Number: 141-163

This supplemental application provides for reducing the lower age limit from 8 to 4 week old and to allow repeat treatment if necessary.

Trade Name:	Milbemite™ Otic Solution
Ingredients:	Milbemycin oxime
Sponsor:	Novartis Animal Health US, Inc.
Approval Date:	December 13, 2000
Status:	Prescription only
Route:	Topical
Species:	Cats and kittens
Drug Form:	Liquid (solution)
Concentration:	0.1%
Indications:	For the treatment of ear mite *(Otodectes cynotis)* infestations in cats and kittens four weeks of age and older.
Patent Number:	4,547,520 Expiration Date: June 14, 2004
Exclusivity:	3 years

21CFR 524.1446

ANADA Number: 200-154

This supplemental application provides for subcutaneous administration of oxytetracycline injectable solution in cattle.

Trade Name:	Pennox™ 200 Injectable
Ingredients:	Oxytetracycline
Sponsor:	Pennfield Oil Company
Approval Date:	January 12, 2001
Status:	Over-the-counter
Route:	Intravenous and subcutaneous in cattle only; intramuscular in cattle and swine
Species:	Cattle and swine
Drug Form:	Liquid (solution)
Concentration:	200 milligrams per milliliter
Indications:	**Cattle (beef cattle, non-lactating dairy cattle, calves including pre-ruminating (veal) calves):** For the treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp., *Haemophilus* spp.; infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*; foot rot and diphtheria caused by *Fusobacterium necrophorum*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresii*; leptospirosis caused *by Leptospira pomona*; and wound infections and acute metritis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline. **Swine:** For the treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*; pneumonia caused *by Pasteurella multocida*; and leptospirosis caused by *Leptospira pomona*. In sows, it is indicated as an aid in the control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli.*
Tolerance:	21CFR 556.500 Oxytetracycline: Tolerances are established for the sum of tetracycline residues in tissues of beef cattle, beef calves, non-lactating dairy cattle, dairy calves, swine, sheep, chickens, turkeys, catfish, lobsters, and salmonids, of 2 parts per million (ppm) in muscle, 6 ppm in liver, and 12 ppm in fat and kidney.
Withdrawal:	Cattle and Swine: 28 days.

21CFR 522.1660

ANADA Number: 200-193

This supplemental application provides for treatment of soft tissue and dental infections in a new species, cats.

Trade Name:	Clindamycin Hydrochloride Oral Liquid
Ingredients:	Clindamycin hydrochloride
Sponsor:	Phoenix Scientific, Inc.
Approval Date:	December 27, 2000
Status:	Prescription only
Route:	Oral
Species:	Cats and dogs
Drug Form:	Liquid (solution)
Concentration:	25 milligrams per milliliter
Indications:	**Cats*:*** For the treatment of soft tissue infections (wounds and abscesses) and dental infections caused by or associated with susceptible strains of *Staphylococcus aureus, Staphylococcus intermedius, Streptococcus* spp., *Bacteroides fragilis,* and *Clostridium perfringens.* **Dogs:** For the treatment of soft tissue infections (wounds and abscesses) and dental infections and osteomyelitis caused by susceptible strains of *Staphylococcus aureus, Bacteroides fragilis, Bacteroides melaninogenicus, Fusobacterium necrophorum* and *Clostridium perfringens*

21CFR 520.447

Change of Sponsor

NADA Numbers: 033-773, 109-471 and 136-214

From: PM Ag Products, Inc.
To: Sweetlix, LLC
175 South Main St., suite 150
Salt Lake City, UT 84111
Drug labeler code: 036904

NADA Numbers: 048-646 and 048-647

From: Wendt Laboratories, Inc.
To: First Priority, Inc.
1585 Todd Farm Dr.
Elgin, IL 60123
Drug labeler code: 058829

NADA and ANADA Numbers:

010-092	**010-346**	**012-123**	**035-157**	**035-455**
035-456	**038-241**	**038-242**	**038-624**	**038-661**
041-955	**044-756**	**055-059**	**093-515**	**095-218**
100-128	**101-690**	**107-506**	**118-032**	**118-979**
120-615	**126-504**	**200-050**	**200-103**	**200-144**

From: Merial, Ltd.
To: Bimeda, Inc.
288 County Rd. 28
LeSuer, MN 56058-9322
Drug labeler code: 061133

Change of Sponsor Name and Address

From: Moorman Manufacturing Co.
Quincy, IL 62301

To: MoorMan's Inc.
1000 North 30th St.
Quincy, IL 62305-3115
Drug labeler code: 021930

Suitability Petition Action

Number: 01P-0124/CP1
Sponsor: First Priority, Inc.
Petition: Request permission to file an ANADA for a generic new animal drug, phenylbutazone, which differs from the pioneer product, Phenylbute™, Phoenix Scientific, Inc., NADA 091-818, by the following characteristics: The proposed generic product dosage form is a chewable tablet.
Action: Filed on March 12, 2001

Number: 01P-0139/CP1
Sponsor: Vetoquinol N.-A., Inc.
Petition: Request permission to file an ANADA for a generic new animal drug, prednisolone, which differs from the pioneer product, PrednisTab®, Lloyd, Inc., NADA 140-921, by the following characteristics: The proposed generic product dosage form is a paste.
Action: Filed on March 21, 2001

Number: 01P-0140/CP1
Sponsor: Vetoquinol N.-A., Inc.
Petition: Request permission to file an ANADA for a generic new animal drug, cefadroxil, which differs from the pioneer product, Cefa-Drops®, Fort Dodge Animal Health, Division of AHP, NADA 140-684, by the following characteristics: The proposed generic product dosage form is a paste.
Action: Filed on March 21, 2001

Number: 01P-0141/CP1
Sponsor: Vetoquinol N.-A., Inc.
Petition: Request permission to file an ANADA for a generic new animal drug, amoxicillin, which differs from the pioneer product, Amoxi-Drop®, Pfizer Inc., NADA 055-085, by the following characteristics: The proposed generic product dosage form is a paste.
Action: Filed on March 21, 2001